IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. 1500 90-TABLET BOTTLES, more or less, of an article of drug . . . and all articles of drugs imported by Local Repack from Genendo Pharmaceutical N.V., . . . Defendants-*in-rem*, and GENENDO PHARMACEUTICAL N.V., a Netherlands Antilles Corporation, Defendant.	)	No. 03 C 6495

MEMORANDUM OPINION AND ORDER

JAMES F. HOLDERMAN, District Judge:

This is an action by the government for the seizure and condemnation of certain prescription drugs and for a permanent inunction. This court has jurisdiction under 28 U.S.C. §§ 1331 and 1345, and under sections 332 and 334 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et seq (the "Act"). Defendant Genendo Pharmaceutical N.V. ("Genendo") has asserted certain affirmative defenses that the prescription drugs, which are the subject of this action, are exempt from seizure and condemnation pursuant to 21 U.S.C. § 353(a) and 21 C.F.R.

§ 201.150 and that the government's requested injunction therefore should not issue.

Genendo is a corporation headquartered in Curacao, Netherlands, Antilles. As a regular part of its business, Genendo purchases, trades and sells pharmaceuticals, including purchasing prescription drugs worldwide and importing them to the United States with the intention that they will be repackaged, relabeled and then distributed to consumers in the United States. Some of the drugs Genendo imports were originally intended for distribution outside of the United States. The prescription drugs that Genendo introduced or caused to be introduced into interstate commerce which are the subject of this action are: Lipitor ("Seized Lipitor"), which Genendo purchased in Brazil; and Zocor ("Imported Zocor"), which Genendo purchased in Argentina. Upon its entry into interstate commerce in the United States, the Imported Zocor, after FDA inspecting and photographing, was delivered to Phil & Kathy's, Inc., of Richton Park, Illinois ("Phil & Kathy's) pursuant to an agreement between that company and Genendo.[1] Genendo had a written agreement with Phil & Kathy's regarding the repackaging and labeling of prescription drugs for human consumption ordered and paid for by Phil & Kathy's. The Seized Lipitor was seized by the government upon its entry into interstate commerce, and was held by the government. It was not delivered to Phil & Kathy's.

The government now seeks condemnation of the Seized Lipitor and a permanent injunction against Genendo. The government does not dispute that the Seized Lipitor and

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[1] The Imported Zocor was seized by the government along with other drugs after reaching Phil & Kathy's. This action was originally commenced by the government only against Phil & Kathy's for seizure of certain articles of drugs. The government's complaint was later amended to include Genendo, and Genendo filed its Statement of Interest as to the Seized Lipitor (Dkt. No. 40). The government and certain principals of Phil & Kathy's entered into a consent decree resolving the claims of the government as to Phil & Kathy's. That consent decree was entered by this court on April 9, 2004. (Dkt. No. 53.)

Imported Zocor each have the same chemical composition, as well as other similarities to the respective drugs Lipitor and Zocor, that are sold legally in the United States. The similarities to the other respective drugs sold as Lipitor and Zocor in the United States notwithstanding, the government argues that the Seized Lipitor and Imported Zocor are subject to condemnation as unapproved new drugs in violation of 21 U.S.C. § 355(a), and misbranded drugs in violation of 21 U.S.C. § 352. Genendo disagrees, and relies upon an exemption embodied in 21 U.S.C. § 353(a) and 21 C.F.R. § 201.150 to argue that condemnation should not occur. Genendo waived its jury demand. A multi-day trial was set to begin on May 2, 2005, but due to the fine efforts and professionalism of counsel, the vast majority of the facts were agreed to and the remaining facts were presented to this court on the single day of May 2, 2005. For the following reasons, this court rules that Genendo by importing the Seized Lipitor and the Imported Zocor into the United States, introduced into interstate commerce unapproved new drugs in violation of 21 U.S.C. § 355(a). This court also grants the government's requested condemnation and injunctive relief as to Genendo's violations of 21 U.S.C. § 355.

COURT'S FINDINGS OF FACT[2]

1. This action arises under the Constitution, laws, or treaties of the United States of America.

2. Plaintiff is the United States of America.

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[2] These facts are the uncontested facts as set forth in Attachment (a) of the Amended Pretrial Order. (Dkt. No. 155.) This court adopts these facts as its own. While evidence was presented to this court on May 2, 2005, none of that evidence is necessary to the disposition of this case. Accordingly, though a large part of Ms. Deborah Autor's testimony on May 2, 2005 was volunteered and impermissible opinion, this court rules as moot Genendo's pending Motion in Limine to Exclude the Trial Testimony of Deborah Autor.

3. This action is one for injunctive relief and seizure and condemnation under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* ("Act").

4. The *in rem* defendants are articles of drugs specifically, 60 boxes of Lipitor containing 10 mg tablets of Lipitor (lot 304-37521) in blister packs of ten tablets per blister sheet, 30 tablets per box, and 48 boxes containing 20 mg tablets of Lipitor (lot 304-37528) in blister packs of ten tablets per blister sheet, 30 per box, located in the northern judicial district of Illinois.

5. A substantial part of the events or omissions giving rise to the claim occurred, or a substantial part of property that is the subject of this action is situated in the northern judicial district of Illinois.

Statutory and Legal Background

6. The United States Food and Drug Administration ("FDA") is authorized to implement, administer, and enforce the Act. 21 U.S.C. § 393(d)(2); 21 U.S.C. § 371(a).

7. Defendant Genendo admits that a drug held for sale in interstate commerce that fails to meet the requirements of 21 U.S.C. § 352(c) and 21 C.F.R. § 201.15(c)(1) is deemed to be misbranded as a matter of law unless exempt by the Act.

8. Genendo admits that the packaging of a drug can be critical to its safety and effectiveness.

9. Genendo admits that 21 U.S.C. § 331(a) prohibits the "introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is adulterated or misbranded."

10. Genendo admits that the Act prohibits distribution in interstate commerce of unapproved new drugs and that the definition of a "new drug" includes any drug, "the

composition of which is such that such drug is not generally recognized among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, . . ." 21 U.S.C. § 321(p)(1).

11. Genendo admits that pursuant to the Act, a manufacturer must obtain FDA approval of a new drug application ("NDA") or an abbreviated new drug application ("ANDA") for each new drug before it may legally be introduced into interstate commerce pursuant to 21 U.S.C. § 355.

12. Genendo admits that an NDA must contain, among other things, information regarding the manufacturer and specification of the drug substance including the name and address of the facility at which it will be manufactured, the process and controls used during manufacturing and packaging, the strength and dosage form of the drug, the specifications related to the drugs' containers and closure systems, and the labeling for the product.

13. Genendo admits that the Act requires that the methods used in, and the facilities and controls used for, the manufacture, processing, packaging, and holding of drugs conform to and be operated and administered in conformity with, current good manufacturing practice ("CGMP").

14. Genendo admits that 21 U.S.C. § 351(a)(2)(B) provides that a drug shall be deemed adulterated "if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of [the Act] as to safety and has the identity and strength, and meets the

quality and purity characteristics, which it purports or is represented to possess." Genendo further admits that the failure to comply with CGMP adulterates a drug as a matter of law.

15. 21 U.S.C. § 353(a) states, in pertinent part:

> The Secretary is directed to promulgate regulations exempting from any labeling or packaging requirement of this chapter drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repackaged in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs and devices are not adulterated or misbranded under the provisions of this chapter upon removal from such processing, labeling, or repacking establishment.

16. The FDA has issued Compliance Policy Guides ("CPG") and other guidance documents relating to, among other things, repacking and labeling of drugs.

Genendo's Activities

17. Genendo is a corporation headquartered in Curacao, Netherlands, Antilles. Genendo, as a regular part of its business either individually or through affiliates, purchases, trades and sells pharmaceuticals.

18. Genendo is not licensed as a drug wholesaler in any state in the United States.

19. Genendo's importation of drugs into the United States has occurred in interstate commerce.

20. Genendo admits that it caused to be imported pharmaceuticals to Phil & Kathy's, on two occasions not related to the *in rem* action involving the Seized Lipitor.

21. Genendo admits that at least some of the prescription drugs that Genendo imported into the United States in 2003 were originally intended for foreign distribution.

22. Genendo admits that some of the drugs that it caused to be imported to Phil & Kathy's Inc., were not labeled in English.

23. Genendo introduced or caused to be introduced the Seized Lipitor in interstate commerce intending to repackage and relabel it.

24. Genendo's prescription drug importation activities are subject to the Act and any exemptions that may be available under the Act and its implementing regulations.

25. The Seized Lipitor bears foreign-language labeling (*i.e.*, Portuguese labeling).

The Seized Lipitor

26. On August 20, 2003, Genendo filed an action for Declaratory Judgment that imports such as the Seized Lipitor were permitted under the Act.

27. The United States moved to dismiss the declaratory judgment action on jurisdictional grounds; specifically, there was no case or controversy because there was no agency action ripe for review.

28. On December 23, 2003, Judge Andersen granted the United States's motion to dismiss.

29. In September, 2003, Genendo advised the United States that it intended to import a shipment of Lipitor.

30. Genendo imported the Lipitor pursuant to an invoice dated September 17, 2003.

31. In an October 24, 2003 letter to the United States Attorney's Office, Genendo advised the United States that it intended to ship the Lipitor imported pursuant to the September 17, 2003, invoice, to be repackaged and labeled and then distributed and dispensed.

32. On or about December 16, 2003, the United States seized the Lipitor that Genendo had imported pursuant to the September 17, 2003, invoice.

33. The Seized Lipitor falls within the meaning of 21 U.S.C. § 321(g), (*i.e.*, articles of

drugs).

34. Lipitor is a "new drug" under 21 U.S.C. § 321(p) of the Act.

35. Pfizer, Inc. ("Pfizer") manufactures Lipitor.

36. Pfizer submitted an NDA for Lipitor to the FDA for approval.

37. FDA assigned the number 20-702 to the Lipitor NDA.

38. FDA approved the NDA for Lipitor submitted by Pfizer.

39. A Pfizer facility located in Loughbeg, Ireland, is identified in the FDA-approved NDA for Lipitor as a manufacturing facility for Lipitor intended for sale and distribution in the United States, including 10 mg and Lipitor 20 mg dosage strengths.

40. FDA has conducted inspections of the Pfizer Loughbeg, Ireland facility that is identified in the approved NDA for Lipitor.

41. In the absence of an exemption, the only labeling that FDA has approved for Lipitor intended for sale in distribution in the United States is English-language labeling.

42. The expiration period in the FDA-approved NDA for Lipitor in blister packages intended for sale or distribution in the United States is two years from the date of manufacture.

43. Genendo purchased the Seized Lipitor in Brazil.

44. Genendo imported the Seized Lipitor into the United States.

45. Lot numbers are used to identify and track a specific batch of a drug.

46. The Lot numbers associated with the Seized Lipitor are:

1. Lot 304-37521 (10 mg); and

2. Lot 304-37528 (20 mg).

47. The Lot numbers are printed on the boxes in which the Seized Lipitor are

packaged.

48. The manufacture dates for each lot of the Seized Lipitor are:

1. Lot 304-37521 - January 16, 2003; and

2. Lot 304-37528 - February 18, 2003.

49. Pfizer shipped the tablets that became the Seized Lipitor from Ireland in bulk containers.

50. The labeling on the Seizer Lipitor is in Portuguese; specifically, each "blister" sheet of 10 tablets and each 30 tablet box bears Portuguese labeling.

51. The package inserts in the boxes of Seized Lipitor are in Portuguese.

52. The Seized Lipitor, which Genendo imported on or about September 30, 2003 bears expiration dates of January 2006 (10 mg, lot 304-37521) and February 2006 (20 mg, lot 304-37528).

53. The Seized Lipitor bears expiration dates more than two years after the date of manufacture.

54. Plaintiff has not conducted any testing on the chemical composition of the Seized Lipitor and accordingly made no allegations in the Complaint that the chemical composition of the Seized Lipitor differs from that of a similar dosage of Lipitor that Pfizer sells in the United States.

55. The FDA-approved NDA for Lipitor lists Lipitor that is destined for sale in the United States to be packed in 100-tablet boxes containing 10 blister cards for 10 tablets.

56. The FDA-approved NDA for Lipitor does not list as packaging for Lipitor that is destined for sale in the United States 30-tablet boxes containing 3 blister cards of 10 tablets.

57. On December 16, 2003, the date of the seizure, the expiration period for the Seized Lipitor had not run.

58. January 16, 2005, was two years from the date of manufacture of the 10 mg Seized Lipitor (lot 304-27521), and February 18, 2005, was two years from the date of manufacture of the 20 mg Seized Lipitor (lot 304-37528). Blister-packed Lipitor that is intended for sale or distribution in the United States is subject to a two-year expiration period.

Imported Zocor

59. The 24,990 tablets of Zocor that are at issue in this case ("Imported Zocor") were manufactured by Merck & Co., Inc. ("Merck").

60. Genendo placed a purchase order for the Imported Zocor in Argentina and the Zocor was shipped from Argentina.

61. The Imported Zocor came from Merck lots A2411M1, A1954L1, A1953L1, A1661L1, and A1954L2.

62. The Imported Zocor is of 40 mg dosage strength.

63. The labeling on the Imported Zocor was in Spanish.

64. The package inserts for the Imported Zocor were in Spanish.

65. Zocor is a "new drug" under 21 U.S.C. § 321(p) of the Act.

66. Merck submitted an NDA for Zocor to FDA for approval.

67. FDA assigned the number 19-766 to the NDA for approval.

68. FDA approved Merck's NDA for Zocor.

69. The FDA-approved NDA for Zocor identifies only Merck facilities located in Caguas and Arecibo, Puerto Rico, as the drug product manufacturing establishments for 40 mg

dosage strength Zocor intended for sale or distribution in the United States.

70. The FDA-approved NDA for Zocor identifies the Merck facility in Cramlington, United Kingdom, as a drug product manufacturing establishment only for 80 mg Zocor.

71. The FDA-approved NDA for Zocor identifies only the Merck facilities located in Caguas, Puerto Rico and Wilson, North Carolina as packaging establishments for Zocor intended for sale or distribution in the United States.

72. The only labeling identified in the FDA-approved NDA for Zocor intended for distribution in the United States is in English.

73. The FDA took photographs of the Imported Zocor prior to its delivery to Phil & Kathy's.

The Agreement with Phil & Kathy's

74. Phil & Kathy's, is an Illinois corporation located in Richton Park, Illinois.

75. Genendo, for some period of time, had a written agreement with Phil & Kathy's, regarding the repackaging and labeling of prescription human drugs ordered and paid for by Phil & Kathy's.

76. Genendo has never had an agreement with any entity other than Phil & Kathy's regarding repackaging and labeling of prescription drugs.

77. Joint Exhibit 12 is the Agreement between Phil & Kathy's and Genendo.

78. Prior to amending the complaint in this action to add Genendo as a defendant, and to seek an injunction against Phil & Kathy's and certain of its principals, the United States filed a seizure action against certain articles of drug located at Phil & Kathy's in Richton Park, Illinois. The United States and certain principals of Phil & Kathy's entered into a consent decree

resolving the United States' claims. The court entered this consent decree on April 8, 2004.

79. 21 C.F.R. § 201.150 was promulgated pursuant to 21 U.S.C. § 353(a).

Likelihood of Recurrence

80. Genendo denies that a drug that does not meet all the requirements of the FDA-approved NDA, including the approved labeling, is an unapproved new drug.

Supplemental Uncontested Facts[3]

Seized Lipitor

81. The Seized Lipitor was manufactured (*i.e.*, formed into tablets) by Pfizer, in Loughbeg, Ireland.

82. www.pfizer.ie includes links to pages stating that Lipitor is manufactured at the Loughbeg Drug Product Plant in Loughbeg, Ireland.

83. Pfizer shipped the tablets that, when packaged, became the Seized Lipitor, in bulk containers to Laboratorios Pfizer Ltda., Guarulhos - SP, Brazil.

84. The Seized Lipitor was packaged in "blister" packs and then in boxes of 30 tablets (3 blister sheets of 10 tablets each) at Laboratorios Pfizer Ltda., Guarulhos - Sao Paulo - SP, Brazil.

85. The only Pfizer manufacturing facilities identified in the FDA-approved NDA for Lipitor are those located in Loughbeg, Ireland, and Vega Baja, Puerto Rico.

86. The only Pfizer packaging facilities identified in the FDA-approved NDA for

[3] These facts have been designated as "Supplemental" because they were agreed to after the pretrial conference on April 27, 2005, and were then added to the uncontested facts through the parties' Agreed Motion to Amend Attachments A, B, C, and E of the Final Pre-Trial Order (Dkt. No. 155.)

Lipitor are those located in Freiburg, Germany and Vega Baja, Puerto Rico.

87. The FDA-approved NDA for Lipitor does not identify any packaging facility in Brazil for Lipitor.

88. The only labeling listed on the FDA-approved NDA for Lipitor is English-language labeling.

89. The expiration period in the FDA-approved NDA for Lipitor in blister packages in the United States is two years from the date of manufacture.

90. FDA has never inspected any Brazilian facility with respect to the packaging of Lipitor.

91. The Brazilian facility where the Seized Lipitor was packaged is not a registered facility pursuant to 21 U.S.C. § 360i with respect to 10mg and 20mg Lipitor.

92. Plaintiff has not conducted any testing of the Seized Lipitor.

93. The United States does not contend the Seized Lipitor is counterfeit within the meaning of the Act.

94. The expiration period for the Seized Lipitor began to run on the day manufacturing was complete.

Imported Zocor

95. In April 2003 Genendo caused to be introduced into interstate commerce 24, 990 tablets of 40 mg Zocor.

96. Genendo caused the Imported Zocor to be imported pursuant an agreement with International Pharmaceutical Exchange ("IPE").

97. Genendo purchased the Imported Zocor in Argentina.

98. The tablets in Zocor lots A2411M1, A1954L1, A1953L1, A1661L1, and A1954L2 were manufactured (granulated, pressed, formed and coated) by Merck (Merck Sharp & Dohme) in Argentina.

99. The tablets in Zocor lots A2411M1, A1954L1, A1953L1, A1661L1, and A1954L2 were packaged in blister packages and then in 30-tablet boxes by Merck (Merck Sharp & Dohme) in Argentina.

100. FDA has never inspected any Argentinian facility with respect to the manufacturing or packaging of Zocor.

101. The FDA-approved NDA for Zocor does not identify any manufacturing or packaging facilities in Argentina for Zocor.

102. The Imported Zocor was delivered to Phil & Kathy's.

The Agreement with Phil & Kathy's

103. In certain circumstances registered firms may repack and label drug products in compliance with the Act and associated regulations.

104. Genendo's intended destination for the Seized Lipitor, prior to the seizure of the Seized Lipitor, was a company called Phil & Kathy's.

105. Genendo introduced the Seized Lipitor in interstate commerce for repacking and relabeling by Phil & Kathy's.

106. Phil & Kathy's d/b/a Local Repack as a repacker and labeler is registered with the FDA as a repacker and labeler and is inspected by the FDA.

107. Registered repackers and labelers routinely repackage and label oral dosage forms of prescription drugs.

108. The Seized Lipitor and Imported Zocor are oral dosage forms of prescription drugs.

Likelihood of Recurrence

109. But for this lawsuit, Genendo would today be importing into the United States solid oral dosage forms of prescription human drugs that do not comply in all respects with FDA-approved NDAs.

LEGAL ANALYSIS AND CONCLUSIONS

The government puts forth two bases for condemnation: (1) the Imported Zocor and Seized Lipitor are unapproved new drugs prohibited by 21 U.S.C. §§ 355(a), 331(d); and (2) the Imported Zocor and Seized Lipitor are misbranded drugs prohibited by 21 U.S.C. §§ 352(c), 331(a). Genendo responds that pursuant to the exemption embodied in 21 U.S.C. § 353(a) and 21 C.F.R. § 201.150 ("§ 353(a) exemption"), the Seized Lipitor is not an unapproved new drug, and that neither the Imported Zocor nor the Seized Lipitor are misbranded. The core dispute in this case is the government's first argument: whether the § 353(a) exemption excuses full compliance with the requirements of the FDA-approved New Drug Application ("NDA") for the respective drugs. As explained below, this court rules that the § 353(a) exemption does not excuse compliance with an FDA-approved NDA's requirements. Thus, as relevant to this case, a new drug's failure to be manufactured and/or packaged according to the exact requirements of an FDA- approved NDA are not exempted by § 353(a) of the Act.

A "new drug" is any drug, "the composition of which is such that such drug is not generally recognized among experts . . . as safe and effective for use . . . ." 21 U.S.C. § 321(p)(1). It is undisputed that the Seized Lipitor and Imported Zocor are both new drugs for

purposes of the Act. (Facts ¶¶ 34, 65.) The Act prohibits the introduction of a new drug into interstate commerce unless that new drug is the subject of an FDA-approved NDA. 21 U.S.C. § 355(a), 331(d).[4] In other words, if a party wishes to introduce into interstate commerce a "new drug," such as the Seized Lipitor and Imported Zocor, that party must first "file with the Secretary" an NDA. 21 U.S.C. § 355(b)(1). That NDA must contain certain information, including: "(A) full reports of investigations which have been made to show whether or not such drug is safe . . .; (B) a full list of the articles used as components of such drug; (C) a full statement of the manufacture, processing, and packaging of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing and packing of such drug; (E) . . . samples of such drug . . . ; [and] (F) specimens of the labeling proposed to be used for such drug." 21 U.S.C. § 355(b)(1). Consistent with § 355(b)(1)(C), the FDA requires that an NDA include detailed information as to the exact facilities that manufacture and process the new drug. 21 C.F.R. § 314.50(d). Upon receipt of an NDA, the FDA reviews it and decides whether or not to approve the NDA. 21 U.S.C. § 355(b)(1). If the FDA does not

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[4] 21 U.S.C. § 355(a) states:

(a) Necessity of effective approval application
No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug.

21 U.S.C. § 331 states in relevant part:

The following acts and the causing thereof are prohibited:
(a) . . .
(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 344, 355, or 360bbb-3 of this title.

approve the NDA for the proposed new drug, then that drug is an unapproved new drug that cannot be introduced into interstate commerce. 21 U.S.C. § 355(a).

Both Lipitor and Zocor are sold legally in the United States pursuant to FDA-approved NDAs. The Seized Lipitor and the Imported Zocor, however, do not comply in all respects with the FDA-approved NDAs for the respective drugs. Pfizer Inc. ("Pfizer") manufactures Lipitor and it is legally sold in the United States pursuant to an FDA-approved NDA. (Facts ¶¶ 35-38.) The only Pfizer manufacturing facilities identified in the FDA-approved NDA for Lipitor are those located in Loughbeg, Ireland, and Vega Baja, Puerto Rico. (*Id.* ¶ 85.) The Seized Lipitor was manufactured in Loughbeg, Ireland. (*Id.* ¶ 81.) The only Pfizer packaging facilities identified in the FDA-approved NDA for Lipitor are those located in Freiburg, Germany and Vega Baja, Puerto Rico. (*Id.* ¶ 86.) The Seized Lipitor was not packaged in either of these facilities, it was packaged at Laboratorios Pfizer Ltda., Guarulhos - Sao Paulo - SP, Brazil. (*Id.* ¶ 84.) The FDA-approved NDA for Lipitor does not identify any packaging facility in Brazil for Lipitor. (*Id.* ¶ 87.) The only labeling listed on the FDA-approved NDA for Lipitor is English-language labeling. (*Id.* ¶ 8.) The Seized Lipitor was not labeled in English, it was labeled in Portugese. (*Id.* ¶ 50-51.)

Merck & Co., Inc. ("Merck") manufactures Zocor and it is legally sold in the United States pursuant to an FDA-approved NDA. (*Id.* ¶¶ 59, 61.) The FDA-approved NDA for Zocor identifies only Merck facilities located in Caguas and Arecibo, Puerto Rico, as the manufacturing facilities for the 40 mg dosage strength Zocor intended for sale in the United States. (*Id.* ¶ 69.) The Imported Zocor is of 40 mg dosage strength. (*Id.* ¶ 62.) The Imported Zocor was manufactured by Merck in Argentina. (*Id.* Supp. ¶ 98, 99.) The FDA-approved NDA for Zocor

does not identify any manufacturing or packaging facilities in Argentina for Zocor. (*Id.* ¶ 101.) The only labeling identified in the FDA-approved NDA for Zocor intended for distribution in the United States is English. (*Id.* ¶ 72.) The labeling on the Imported Zocor was not in English, but in Spanish. (*Id.* ¶ 63.)

The failure of the Seized Lipitor and the Imported Zocor to comply with the requirements of the FDA-approved NDAs means that those drugs cannot be introduced into interstate commerce under the cover of the respective FDA-approved NDAs. An FDA-approved NDA is in effect an approved "recipe" for making a drug. *See United States v. Baxter Healthcare Corp.*, 901 F.2d 1401, 1412 (7th Cir. 1990). That recipe includes not only the chemical composition of the drug, but also the procedure used in creating the drug. As the Seventh Circuit stated, the detailed requirements of the new drug approval process of § 355 reflect "a Congressional view that the way in which drugs are mixed and packaged is no less important than the chemical makeup of the drugs." *Id.* at 1411. Therefore, it is not enough that the Imported Zocor and Seized Lipitor share the same chemical makeup of FDA-approved Zocor and Lipitor sold in the United States. To be introduced into interstate commerce under the cover of an FDA-approved NDA, the drugs must comply with all requirements of that NDA. *Id.* The drugs at issue here do not. The Imported Zocor was manufactured at a facility not listed on the FDA-approved NDA for Zocor. The Seized Lipitor was packaged at a facility not listed on the FDA-approved NDA for Lipitor. Accordingly, the FDA has not approved the conditions under which the Imported Zocor was manufactured, and, similarly, the FDA has not approved the conditions under which the Seized Lipitor was packaged. The failure to comply with the requirements of the FDA-approved NDAs means that the Imported Zocor and Seized Lipitor cannot be introduced into

interstate commerce pursuant to the FDA-approved NDAs for Zocor and Lipitor. The result is that the Imported Zocor and Seized Lipitor are unapproved new drugs that cannot lawfully be introduced into interstate commerce. 21 U.S.C. § 355(a), 331(d).

Genendo concedes, as it must, that the Imported Zocor is an unapproved new drug because it was manufactured at a location not listed on the FDA-approved NDA.[5] As to the Seized Lipitor, however, Genendo argues that its failure to comply with the FDA-approved NDA's packaging requirement is excused by the § 353(a) exemption, and, that if the Seized Lipitor had been allowed to be repackaged at a facility (regardless of whether that facility is listed on the relevant FDA-approved NDA) "it would have been in complete compliance with the Act." (Dkt. No. 172 at 22.) This court disagrees. The § 353(a) exemption states, in relevant part:

> The Secretary is directed to promulgate regulations exempting from any labeling or packaging requirement of this chapter drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed . . . .

21 U.S.C. § 353(a). The FDA promulgated 21 C.F.R. § 201.150 in response to the § 353 exemption. According to Genendo, the FDA must recognize the Seized Lipitor as exempted from the FDA-approved NDA's "packaging requirement," because the Seized Lipitor will be "repacked" at an establishment "other than [that] where originally . . . packed" pursuant to the § 353(a) exemption. 21 U.S.C. § 353(a).

It is clear, as the government argues, that to accept Genendo's argument regarding the § 353(a) exemption would necessarily lead to the evisceration of the protections afforded by the

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[5] As stated in its Closing Argument, "Genendo does not contend that the imported drugs need not be manufactured, as opposed to packaged or labeled, in a facility listed on the NDA . . . ." (Dkt. No. 172, at 14 n.10.)

new drug approval process. The Seized Lipitor was not packaged at a facility listed on the FDA-approved NDA, and Genendo has no intention of having the Seized Lipitor, or any other similar drug that it might import, packaged at facilities listed on the relevant FDA-approved NDA. Genendo's position is that because of the § 353(a) exemption, the labeling and packaging requirements of the FDA-approved NDA are "irrelevant." (Dkt. No. 172 at 21.) In support, Genendo argues that to rule otherwise would eviscerate the § 353(a) exemption. Thus, the issue this court is presented with, as Genendo frames it, is to either side with the government, thereby eviscerating the § 353(a) exemption, or to side with Genendo, thereby eviscerating the new drug approval process.

If compelled to choose, this court would eviscerate the § 353(a) exemption and leave the new drug approval process unscathed. As the Supreme Court has recognized, the Act "touch[es] phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection," *United States v. Dotterweich*, 320 U.S. 277, 280 (1943), and as such it is a "well-accepted principle that [the Act] is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health." *Baxter*, 901 F.2d at 1408 (quoting *United States v. An Article of Drug . . . Bacto-Unidisk . . .*, 394 U.S. 784, 798, 89 S.Ct. 1410, 1418, 22 L.Ed.2d 726 (1969)). Maintaining the panoply of the new drug approval process at the expense of the § 353(a) exemption is more consistent with protecting the public health than avoiding interfering with certain commercial activity at the expense of the new drug approval process. Therefore, if necessary, the § 353(a) exemption must give way to the new drug approval process.

This court, however, has an "obligation to construe the two statutory provisions at issue

in this case in such a way as to avoid conflicts between them, if such a construction is possible and reasonable." *Precision Indus., Inc. v. Qualitech Steel SBQ, LLC*, 327 F.3d 537, 544 (7th Cir. 2003). As the Supreme Court observed, and the Seventh Circuit reiterated:

> [W]e 'are not at liberty to pick and choose among congressional enactments, and when two statutes are capable of co-existence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective.' *Morton v. Mancari*, 417 U.S. 535, 551, 94 S.Ct. 2474, 2483, 41 L.Ed.2d 290 (1974). We should read federal statutes 'to give effect to each if we can do so while preserving their sense and purpose.' *Watt v. Alaska*, 451 U.S. 259, 267, 101 S.Ct. 1673, 1678, 68 L.Ed.2d 80 (1981); see also *United States v. Fausto*, 484 U.S. 439, 453, 108 S.Ct. 668, 676-77, 98 L.Ed.2d 830 (1988).

Precision Indus., Inc., 327 F.3d at 544 (citations omitted). The new drug approval process embodied in § 355 and the § 353(a) exemption can be construed in a way "to give effect to each . . . while preserving their sense and purpose." *Id.* This requires distinguishing between general "labeling" and "packaging" requirements and the "labeling" and "packaging" requirements of an FDA-approved NDA. The former are regulated in various ways by the Act, 21 U.S.C. § 352, but the latter are given special treatment under the Act in that they are ingredients of an FDA-approved recipe as provided for in § 355. As the government correctly argues, the "packaging" and "labeling" ingredient of an FDA-approved NDA includes more than just a type of packaging with descriptive terms. It also includes the "methods used in, and the facilities and controls used for, the . . . processing and packing of such drug." 21 U.S.C. § 355(b)(1)(D). Thus, according to the plain language of the statute, the packaging of a new drug does not just refer to the material that encases a drug, but also includes the method by which the drug is packaged and the facility where the drug is packaged. Genendo, through its repacker, may be able to replicate the type of packaging material, but it cannot replicate the combination of the FDA-approved facility and

method for packaging as to a specific drug.

Nothing in the plain language of the exemption, or in the legislative history provided to the court by the parties, suggests any intent on the part of Congress to allow any drug importer to make changes to the FDA-approved NDA for a drug.[6] In fact, the Act has detailed provisions for approving changes to an already approved NDA. 21 U.S.C. § 356a; 21 C.F.R. § 314.70. In other words, nothing in the § 353(a) exemption suggests an intent to exempt changes in the FDA-approved recipe for a new drug, and this court will not construe the statutory provisions to allow Genendo to make such changes. *Spokane & Inland Empire RR Co. v. United States*, 241 U.S. 344, 350 (1916) ("[e]xceptions from a general policy which a law embodies should be strictly construed; that is, should be interpreted as not to destroy the remedial process intended to be accomplished by the enactment.") Reading the § 353(a) exemption to apply to "labeling" and "packaging" requirements, but not to the detailed requirements of an FDA-approved NDA, which admittedly include labeling and packaging requirements, gives the exemption effect without intruding on the new drug approval process.

This conclusion is not affected by *United States v. Kaybel*, 430 F.2d 1346 (3d Cir. 1970) as Genendo argues. In *Kaybel,* the defendants were charged with criminal violations of the Act for introducing into interstate commerce unapproved new drugs, or, in other words, the defendants were charged with distributing new drugs for which no FDA-approved NDA was

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[6] The First Circuit has explained that the purpose of the § 353(a) exemption was to "avoid unwarranted interferences with certain legitimate commercial operations, such as the canning of food at branch canneries and delivery to a central plant for labeling, or the bulk shipment of crude drugs for processing and repacking before distribution to consumers." *Arner Co. v. United States*, 142 F.2d 730, 734 n.3 (1st Cir. 1944) (*citing* Sen. Rep. No. 493, 73rd Cong., 2d Sess., 1934).

effective. *Id.* at 1347. Specifically, the defendants were distributing into interstate commerce Enovid 5 mg. *Id.* As the Third Circuit explained, that Enovid 5 mg. was sold legally in the United States pursuant to an FDA-approved NDA:

> Before placing [the Enovid 5mg.] on the market, [the original manufacturer] filed a new drug application with the Food and Drug Administration as required by the Food, Drug, and Cosmetic Act. 21 U.S.C. § 355. The application was approved and became effective on March 9, 1961. While this approval was in effect, [the defendants] *repackaged* Enovid 5 mg. tablets *from the manufacturer's original 500-unit bottles* into its own 100-unit bottles, and sold the repackaged drug in interstate commerce.

Id. at 1347. What is important to note from this excerpt is that the defendants in *Kaybel* were repackaging drugs that were compliant with an FDA-approved NDA. The Third Circuit eventually held that the repackaging of drugs that were compliant with an FDA-approved NDA did not violate § 355. But in this case, the Seized Lipitor was not compliant with an FDA-approved NDA, and Genendo has no intention of making the Seized Lipitor compliant because Genendo did not intend to have the drug packaged or repackaged at a facility listed on the FDA-approved NDA for Lipitor. Thus, *Kaybel* is distinguishable from this case. And even if *Kaybel* supported the proposition that a new drug need not be packaged according to the requirements of an FDA-approved NDA, this court believes that view would be inconsistent with that espoused by the Seventh Circuit. *Baxter*, 901 F.2d at 1412 (explaining that § 355 "reflects a Congressional view that the way in which drugs are mixed and packaged is no less important than the chemical makeup of the drugs).

Accordingly, as to the Seized Lipitor, this court rules that it is subject to condemnation as

an unapproved new drug.[7] 21 U.S.C. §§ 334, 355(a). The Seized Lipitor is a new drug. It is not the subject of an FDA-approved NDA because it does not comply with all the requirements of the relevant FDA-approved NDA. Finally, its lack of compliance with an FDA-approved NDA is not excused by § 353(a), because that statutory provision does not provide an exemption from the new drug approval requirements of § 355.

The government has also requested injunctive relief pursuant to § 332(a), which this court finds appropriate and necessary with regard to Genendo's activity of introducing into interstate commerce drugs prohibited by § 355. When the government seeks an injunction pursuant to a statute protecting the public health, the government need only show that the defendant has violated the statute and that there is some "cognizable danger of recurrent violations." *United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953); *SEC v. Holschuh*, 694 F.2d 130, 144 (7th Cir. 1982). Genendo has at least twice introduced or caused to be introduced into interstate commerce drugs that violate § 355 of the Act. Such past misconduct is "highly suggestive of the likelihood of future violations." *CFTC v. Hunt*, 591 F.2d 1211, 120 (7th Cir. 1979) (citation omitted). It is also significant that Genendo has continued to assert that its conduct does not violate the Act. *Id.* Finally, it is an uncontested fact, that "[b]ut for this lawsuit, Genendo would today be importing into the United States solid oral dosage forms of prescription human drugs that do not comply in all respects with FDA-approved NDAs." (Facts ¶ 109.) Given this admission from Genendo that absent legal action it will continue to import drugs that violate

[7] The court rules, even though Genendo has already conceded it, that the Imported Zocor is also an unapproved new drug. 21 U.S.C. §§ 355(a), 331(d).

§ 355, it is clear that injunctive relief is necessary to prohibit Genendo from introducing into interstate commerce unapproved new drugs prohibited by § 355.[8]

[8] The court's ruling makes it unnecessary to rule on the other issues presented by the parties. As Genendo's activities at issue here do not fall within the § 353(a) exemption, it is unnecessary to determine whether the agreement Genendo had with Phil & Kathy's satisfies the requirements of 21 C.F.R. § 201.150. Furthermore it is unnecessary for this court to determine the overlapping issue of whether the drugs in this case are also misbranded pursuant to 21 U.S.C. § 352(c). The injunction this court is issuing barring Genendo from introducing into drugs into interstate commerce that violate § 355 will prohibit the introduction of drugs like the Imported Zocor and Seized Lipitor. There are no facts in the record indicating that Genendo has or will violate § 352(c) without also violating § 355, and the uncontested facts establish only that Genendo, absent this lawsuit, intended to continue to import drugs that "don not comply in all respects with FDA-approved NDAs." (Facts ¶ 109.) This court has enjoined that activity. Therefore, any drugs Genendo imports must be NDA compliant, which means the drug's labeling must comply with the relevant FDA-approve NDA. 21 U.S.C. § 355(b)(1)(F).

CONCLUSION

Accordingly, the Seized Lipitor is subject to condemnation, and, therefore, the government may proceed to condemn the Seized Lipitor under 21 U.S.C. § 334(a) because it is an unapproved new drug that has been introduced into interstate commerce as prohibited by § 355(a). Genendo violates 21 U.S.C. § 331(d) by introducing into interstate commerce and causing the introduction and delivery for introduction into interstate commerce "new drugs" within the meaning of 21 U.S.C. § 321(p), which do not comply with the specifications of a New Drug Application approved by FDA that meets the requirements of 21 U.S.C. § 355(b) and (d). Defendant Genendo, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with them who receive actual notice of this order by personal service or otherwise are hereby permanently enjoined from introducing into interstate commerce unapproved new drugs in violation of 21 U.S.C. §§ 331(d); 355.

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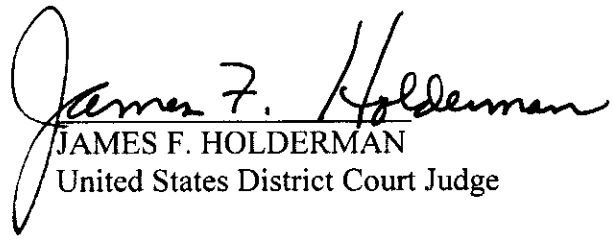

JAMES F. HOLDERMAN
United States District Court Judge

Date: August 12, 2005.